PATENT
Customer Number 22,852
Attorney Docket No. 03806.0500

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Francoise LECLERC *et al.*	)	Group Art Unit: To Be Assigned
	)	
Serial No.: To Be Assigned	)	Examiner: To Be Assigned
	)	
Filed: February 16, 2001	)	
	)	
For: PROCESS FOR PREPARING FUNCTIONALIZED POLYALKYLENEIMINES, COMPOSITIONS CONTAINING THEM AND USES THEREOF	)	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

PRELIMINARY AMENDMENT

Prior to the examination of the above application, please amend this application as follows:

IN THE SPECIFICATION:

Please insert the following before the first sentence:

-- This application claims the benefit of French Patent Application No. 0002059, filed February 18, 2000, and of U.S. Provisional Application No. 60/203907, filed May 12, 2000, which are hereby incorporated herein by reference.--

IN THE CLAIMS:

Please cancel claims 1-22 without prejudice or disclaimer of the subject matter recited therein and add claims 23-42 as follows:

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--23. A process for making functionalized polyalkyleneimines, comprising treating a polyalkyleneimine with a functionalized hemiacetal in the presence of titanium (IV) isopropoxide and sodium borohydride.

24. The process according to claim 23, further comprising an alcoholic solvent.

25. The process according to claim 24, wherein the alcoholic solvent is methanol or ethanol.

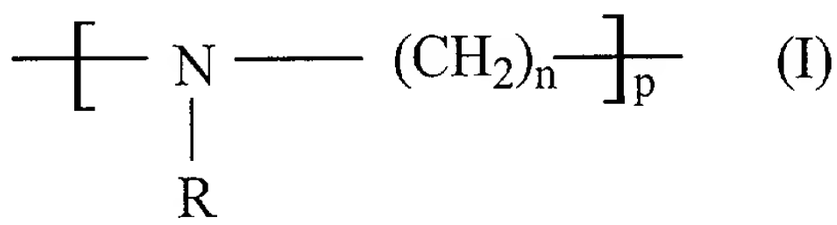
26. The process according to claim 23, which is performed at a temperature between about 10°C and about 30°C.

27. The process according to claim 23, wherein between about 25 mol and about 100 mol of titanium (IV) isopropoxide are used per mol of polyalkyleneimine.

28. The process according to claim 23, wherein a molar amount of sodium borohydride is used equal to between 50% and 80% of the molar amount of titanium (IV) isopropoxide.

29. The process according to claim 23, wherein between about 6 mol and about 100 mol of functionalized hemiacetal are used per mol of polyalkyleneimine.

30. The process according to claim 23, wherein the polyalkyleneimine has the general formula:



(I)

wherein R is hydrogen or a group of the general formula:

(II)

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wherein n is an integer between 2 and 10 inclusive;

wherein p and q are integers; and

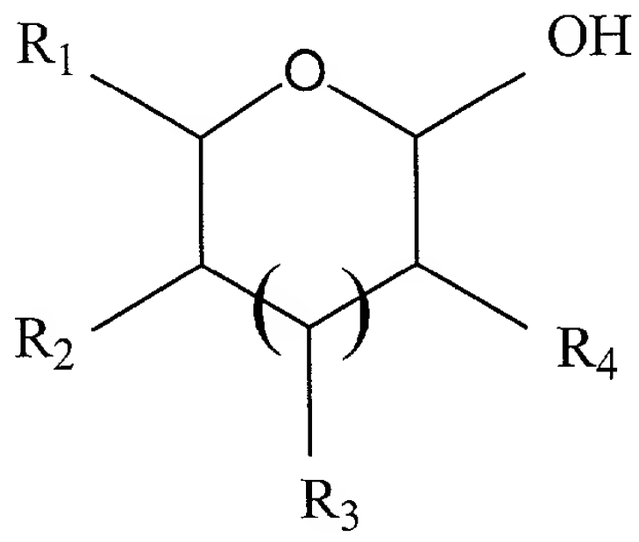
wherein the sum of p + q is such that an average polymer molecular weight is between about 100 Da and about 10^7 Da.

31. The process according to claim 30, wherein the polyalkyleneimine is polyethyleneimine or polypropyleneimine.

32. The process according to claim 31, wherein the polyethyleneimine has an average molecular weight of about 50,000 Da, about 25,000 Da, or about 22,000 Da.

33. The process according to claim 31, wherein the polypropyleneimine has an average molecular weight of about 800,000 Da.

34. The process according to claim 23, wherein the functionalized hemiacetyl has the general formula:



wherein n is 0 or 1;

R_1, R_2, R_3, and R_4 are independently hydrogen, a group compatible with the reaction carried out, or a targeting element; and

only one of R_1, R_2, R_3, and R_4 is a targeting element.

35. The process according to claim 34, wherein the group which is compatible with the reaction is chosen from hydroxyls, C1-C4 alkyls, and C1-C4 hydroxyalkyls.

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36. The process according to claim 34, wherein the targeting element is chosen from sugars, peptides, proteins, oligonucleotides, lipids, neuromediators, hormones, vitamins, and derivatives thereof.

37. The process according to claim 34, wherein the targeting element is chosen from growth factor receptor ligands, cellular lectin receptor ligands, cytokine receptor ligands, ligands of RGD sequences with an affinity for the receptors of adhesion proteins, transferrin receptors, high density lipoproteins, low density lipoproteins, the folate transporter, Sialyl Lewis X, antibody fragments, single-chain antibodies (ScFv), monoglycerides, diglycerides, and triglycerides.

38. The process according to claim 37, wherein between about 1% and about 20% of the functionalized hemiacetyl is grafted onto the polyalkyleneimine.

39. A composition comprising at least one polyalkyleneimine prepared according to the process of claim 23 and at least one nucleic acid.

40. The composition according to claim 39, wherein the nucleic acid is a deoxyribonucleic acid or a ribonucleic acid.

41. The composition according to claim 40, wherein the nucleic acid comprises a gene of therapeutic interest under the control of regulatory sequences.

42. A method for transferring nucleic acids into cells comprising preparing the composition according to claim 39 and contacting said cells with the composition under conditions which allow DNA transfer.--

REMARKS

Applicants have canceled claims 1-22 and added new claims 23-42 to conform to standard U.S. practice. Support for claims 23-42 can be found in the canceled claims and in the specification.

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If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: February 16, 2001

By: _____
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